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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,348	02/24/2004	Susan Shelso	1001.1725101	8750

28075 7590 08/12/2010

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EXAMINER
SCHELL, LAURA C

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
08/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,348	SHELSO ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,12,16,17,19,21-23 and 40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,12,16,17,19,21-23 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 12, 16, 17, & 19-23 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (US 2003/0125751) in view of Muni et al. (US Patent No. 5,316,706) and further in view of Van Tassel et al. (US Patent No. 4,531,943). Griffin discloses the device substantially as claimed including a medical device comprising: a guidewire (Fig. 6a discloses an embodiment with a guidewire (21)) having a first diameter (diameter of the guidewire 21) and a distal stop having a second diameter greater than the first diameter (distal stop is 29 which has a different diameter; also see paragraph [0187]); an elongate tubular member (Figs. 49 and 50, 210) having a proximal end (near 2) and a distal end (near 31) with a guide wire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter

of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen within it that snugly encompasses the diameter of the guidewire); and a tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202) disposed at the distal end of the elongate tubular member and having a distal end (near 202), a proximal end (near 5) and a tip lumen therethrough (lumen which 21 passes through), the tip having an elastic portion (portion 31 is an elastic portion) and a radially inextensible distal portion distal of the elastic portion (202 is distal of elastic portion 31 and is radially in extensible; Figs. 46 and 47 as well as paragraph [0302] and Figs. 37-39 disclose that the distal end of the catheter is made of flexible material, designed to deform upon compression and contact. Furthermore, paragraph [0303] discloses that the radially inextensible ring acts as a stop when contacting the filter. Also see paragraphs [0266], [0267] and [0303] which disclose that portion 31 is a deformable polymeric material but portion 202 is a harder material which acts as a stop when it abuts the stop on the guidewire and prevents the distal end of the catheter from deforming around the stop of the guidewire); wherein the elongate tubular member is slidably disposed on the guidewire such that the distal end of the tip engages against eh distal stop when the elongate tubular member is advanced distally relative to the guidewire (wherein the radially inextensible distal portion is a distal most extremity (the catheter is perfectly capable of performing this function); Figs. 46, 47, 49 and 50 disclose that the very distal tip of 202 is the distal-most extremity of the catheter), wherein the tip is configured to invert proximally into the lumen (it is the examiner's position that the tip is perfectly capable of inverting proximally into the lumen if enough

pressure is applied to the tip when it abuts an object such as the guidewire stop. The tip is capable of such a deformation if the right conditions are present, and therefore is capable of meeting this functional language). Griffin, however, does not disclose that the tip comprises an amorphous polymer or that the radially inextensible distal portion comprises a locally crystalline section thereof or that the distal end of the tip is configured to invert proximally into the tip lumen upon engaging the distal stop.

Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness. Specifically, col. 4, lines 18-22 disclose that catheter does not have to be limited to the stiff portion being the body portion and the soft portion being the tip, and also discloses that the crystallinity may be "varied in any of a plurality of zones throughout the length" thus indicating that many different portions can be soft or crystallized, depending on what is preferred. Therefore it would have been obvious to one of ordinary skill in the art, due to this teaching to have made a portion distal of the amorphous portion of the tip, crystalline). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for the catheter, especially

since Muni discloses that the regions of crystalline and the softer amorphous polymer regions can be varied.

Van Tassel discloses a similar catheter (Figs. 4 and 5) and further discloses that the shape of the distal tip of the catheter is such that when it contacts a surface it allows the distal end of the tip to invert proximally into the tip lumen (Fig. 5). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin in view of Muni with the shape of the distal tip which allows inversion into the tip lumen, as taught by Van Tassel, as this would have involved a change in shape of the tip and a change in shape is generally recognized as being within the level of ordinary skill in the art.

In reference to claim 12, Griffin discloses that the radially inextensible distal portion comprises a ring having a lumen therethrough (Figs. 49 and 50 disclose that 202 has a lumen through it).

In reference to claims 16 and 17, as defined by MPEP 2113, product by process claims are not limited to the recited steps, only the structure implied by the steps. Therefore the distal portion is anticipated by Griffin.

In reference to claim 19, Griffin discloses that the radially inextensible distal portion comprises a non-compliant plastic band (paragraph [0303]).

In reference to claim 20, Griffin discloses that the tip further comprises a flexible portion proximate the radially inextensible distal portion (portion 31 is more flexible than portion 202; see paragraph [0303]).

In reference to claim 21, Griffin discloses that the flexible portion is proximal of the radially inextensible distal portion (portion 31 is proximal to 202), wherein the flexible portion tapers from a first outer diameter at a first location along the tip to a second outer diameter less than the first outer diameter at a second location along the tip distal of the first location (see Figs. 49 and 50 and the marked-up version of Fig. 49 at the end of the office action).

In reference to claim 22, Griffin discloses that at the first location along the tip, the tip has a first thickness and a first inner diameter, and wherein at the second location along the tip distal of the first location, the tip has a second thickness less than the first thickness and a second inner diameter greater than the first inner diameter (see Fig. 49 and the marked up version of Fig. 49 at the end of the office action).

In reference to claim 23, Griffin discloses that the flexible portion comprises an inner surface concave in a first plane normal to a longitudinal axis and a second plane normal to the first plane (Fig. 49).

In reference to claim 38, Van Tassel discloses that the tip lumen comprises a cavity within the tip, wherein the cavity forms a concave hollow that is larger in diameter than the inner diameter of the guidewire lumen (Figs. 4 and 5 hollow 27).

Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (US 2003/0125751) in view of Muni et al. (US Patent No. 5,316,706) and further in view of Van Tassel et al. (US Patent No. 4,531,943). Griffin discloses the

device substantially as claimed including a medical device comprising: a guidewire (Fig. 6a discloses an embodiment with a guidewire (21)) having a first diameter (diameter of the guidewire 21) and a distal stop having a second diameter greater than the first diameter (distal stop is 29 which has a different diameter; also see paragraph [0187]); an elongate tubular member (Figs. 49 and 50, 210) having a proximal end (near 2) and a distal end (near 31) with a guide wire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen within it that snugly encompasses the diameter of the guidewire); an integrally formed tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202) disposed at the distal end of the elongate tubular member and having a distal end (near 202), disposed at the distal end of the elongate tubular member and having a proximal end (near 5) and a tip lumen therethrough (lumen which 21 passes through), in fluid communication with the guidewire lumen; wherein the tip having an elastic portion (portion 31 is an elastic portion) and a radially inextensible distal portion distal of the elastic portion (202 is distal of elastic portion 31 and is radially in extensible; Figs. 46 and 47 as well as paragraph [0302] and Figs. 37-39 disclose that the distal end of the catheter is made of flexible material, designed to deform upon compression and contact. Furthermore, paragraph [0303] discloses that the radially inextensible ring acts as a stop when contacting the filter. Also see paragraphs [0266], [0267] and [0303] which disclose that portion 31 is a deformable polymeric material but portion 202 is a harder material which acts as a stop when it abuts the stop on the guidewire and

prevents the distal end of the catheter from deforming around the stop of the guidewire); wherein the elongate tubular member is slidably disposed on the guidewire such that the distal end of the tip engages against the distal stop when the elongate tubular member is advanced distally relative to the guidewire (wherein the radially inextensible distal portion is a distal most extremity (the catheter is perfectly capable of performing this function); Figs. 46, 47, 49 and 50 disclose that the very distal tip of 202 is the distal-most extremity of the catheter), wherein the tip is configured to invert proximally into the lumen (it is the examiner's position that the tip is perfectly capable of inverting proximally into the lumen if enough pressure is applied to the tip when it abuts an object such as the guidewire stop. The tip is capable of such a deformation if the right conditions are present, and therefore is capable of meeting this functional language). Griffin, however, does not disclose that the tip comprises an amorphous polymer or that the radially inextensible distal portion comprises a locally crystalline section thereof or that the distal end of the tip is configured to invert proximally into the tip lumen upon engaging the distal stop.

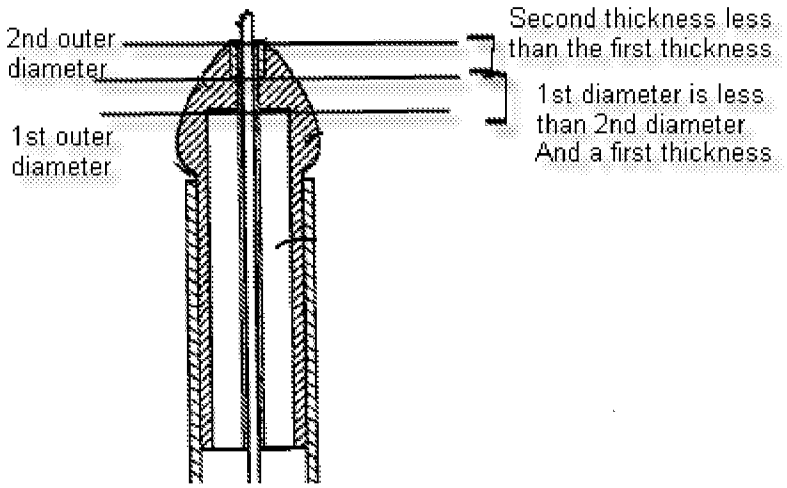
Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness. Specifically, col. 4, lines 18-22 disclose that catheter does not have to be limited to the stiff portion being the body portion and the soft portion

being the tip, and also discloses that the crystallinity may be "varied in any of a plurality of zones throughout the length" thus indicating that many different portions can be soft or crystallized, depending on what is preferred. Therefore it would have been obvious to one of ordinary skill in the art, due to this teaching to have made a portion distal of the amorphous portion of the tip, crystalline). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for the catheter, especially since Muni discloses that the regions of crystalline and the softer amorphous polymer regions can be varied.

Van Tassel discloses a similar catheter (Figs. 4 and 5) and further discloses that the shape of the distal tip of the catheter is such that when it contacts a surface it allows the distal end of the tip to invert proximally into the tip lumen (Fig. 5). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin in view of Muni with the shape of the distal tip which allows inversion into the tip lumen, as taught by Van Tassel, as this would have involved a change in shape of the tip and a change in shape is generally recognized as being within the level of ordinary skill in the art.

In reference to claim 41, Van Tassel discloses that the inverted tip stores energy that is released when the tip returns to an everted state, and the stored energy theists in peeling the tip off of the distal stop (Figs. 4 and 5).

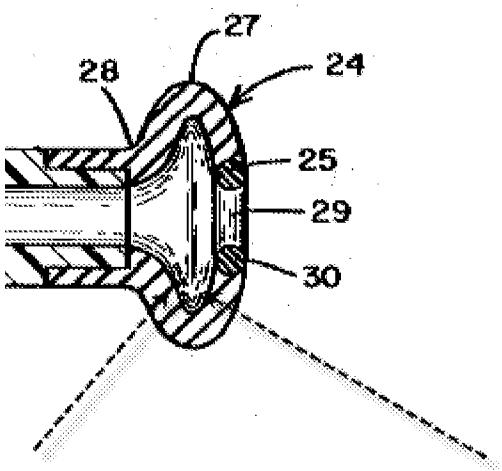
In reference to claim 42, Van Tassel discloses that releasing the stored energy provides tactile feedback to an operator of the medical device (Figs. 4 and 5).



Response to Arguments

Applicant's arguments filed 6/9/2010 have been fully considered but they are not persuasive. Applicant argues that in order for the combination of above references to work, the filter in the Griffin reference would have be removed, however the claim language does not state that the distal tip of the catheter must directly contact the distal stop. Griffin's catheter can be interpreted to engage the distal stop via it's engagement with the stops on the filter device, wherein enough forceful contact with the ends of the filter device may provide the same stopping action as the catheter itself coming into direct contact with the distal stop. Applicant further argues that Muni does not disclose

a tip with a hardened crystalline portion. However, as referenced in the rejection above, Muni discloses that the pattern of soft amorphous portions and hardened crystalline portions can be varied, thus indicating that it is possible to have a tip with a hardened crystalline portion. Applicant also argues that the Van Tassel reference does not show the tip inverting into the proximal portion of the tip lumen. It is the examiner's position, however, that the inner wall portions bordering the hinge line in the tip portion, are not contacting each other, thus there is space between the inner wall portions on either side of the hinge line for the wall portions to come closer together and contact each other, which would result in the tip inverting into the proximal portion of the lumen if a force is applied that results in pushing the inner wall portions together. Therefore it is the examiner's position that Van Tassel discloses a device which is perfectly capable, if not configured to provide a tip that can invert into the proximal portion of the lumen. The examiner thinks it would greatly help advance prosecution if the independent claim language were amended to recite the structural differences (varying diameter of the tip lumen along the length of the tip, thickness of the wall at points along the length of the tip lumen, etc.) found in Applicant's Figs. 3-5 as compared to the cited references.



The arrows point to portions of the inner wall on either side of the hinge line. Since the inner wall on either side of the hinge line is not in contact with itself, space exists for the distal tip to move further and have the inner wall on either side of the hinge line come into contact with itself, which would result in the tip inverting into the tip lumen

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767